

REMARKS

A new claim, claim 3, has been added to the application to recite that the engaged portion for engaging the engaging hooks on the clamp of the present invention comprises notches or holes provided in the lower member. New claim 3 is supported by the description in the specification on page 8, lines 17-21.

Reconsideration of the 35 U.S.C. § 102 rejection of claim 1 is respectfully requested. The Chamuel reference relied on by the Office is not sufficient, for the reasons explained below, to support anticipation of claim 1 under 35 U.S.C. § 102. More specifically, Chamuel is insufficient to support anticipation of claim 1 under 35 U.S.C. § 102 because Chamuel fails to disclose, expressly or inherently, each and every limitation of the claim.

First, claim 1 recites that the upper member of the clamp of the invention is provided with a pair of left and right engaging hooks at its distal end, and that the lower member is provided with an engaged portion for engaging said engaging hooks. The Office has asserted that Chamuel discloses that the upper member of the needle safety clip disclosed therein is provided with a pair of left and right engaging hooks (28' in Fig. 4) and that the lower member is provided with "an engaged portion" (Action, page 3, line 2). However, the Office has not identified the engaged portion or

otherwise explained its position that Chamuel discloses an engaged portion.

Contrary to the position of the Office, Chamuel nowhere discloses that the member of the safety clip opposite the member provided with the "engaging hooks" 28' in Fig. 4 (or the safety clip of any of the other drawings) engages, touches or otherwise contacts any portion of the member provided with the engaging hooks. Chamuel discloses only that:

"[w]hen sliding surface 32 goes beyond the injecting end or point of the needle 24 as illustrated in Fig. 3, the needle no longer counters the force exerted by the compression portion 30 and contact surface 32 is actuated downward through the axis of the needle 24. Abutting engagement surface 34 engages the injecting end in abutting relation and a friction engagement surface 36 snaps against a portion of needle 24 so as to engage the safety clip."

(Col. 3, lines 34-42) (Emphasis added). The clip of Fig. 4 is disclosed as functioning substantially the same as the clip of Fig. 3. (See Col. 3, lines 50-57).

Moreover, a disclosure in Chamuel of a safety clip having an engaged portion, per se, will not support anticipation of the clamp recited in claim 1 of the present application. Claim 1 requires that the engaged portion be provided for engaging the engaging hooks. Chamuel nowhere discloses or shows an engaged portion on

one of the members of the safety clip for engaging engaging hooks on the other member.

Applicants note that the impropriety of the anticipation rejection is supported by the fact that the recitation in claim 1:

"wherein the upper member is provided with a pair of left and right engaging hooks at its distal end, and the lower member is provided with an engaged portion for engaging said engaging hooks"

was originally recited in claim 2. Claim 2, however, was never rejected for anticipation over Chamuel.

If the Office maintains the 35 U.S.C. § 102 rejection, it is respectfully requested to identify or explain the engaged portion for engaging engaging hooks in the safety clip of the Chamuel reference.

Second, claim 1 recites that the clamp of the invention is "to be placed and used on the tube of a winged needle and for storing the needle after use, the winged needle including a needle cannula, a hub with a wing, and a tube connected to the hub", and that the clamp includes "a pressurizing portion provided on said upper member or lower member for engaging and pressurizing said tube when said members are engaged". The Office has taken the position that the first quoted recitation has not been given patentable weight because it occurs in the preamble. The Office notes that a preamble is generally not given any patentable weight where it

merely recites the intended use of a structure or where the body of the claim does not depend on the preamble for completeness.

The position of the Office is not correct. More recent case law relating to the effect of a preamble provides that "a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 [62 USPQ2d 1781] (Fed. Cir. 2002). In the present case, the preamble is necessary to give meaning to the claim. The recitation defines and limits the environment in which the clamp is to be used and inherently requires that the clamp have a structure that allows it to be placed and used on the tube (connected to a hub) of a winged needle.

Regarding the second quoted limitation, the clamp for a winged needle of the present invention is initially provided on a tube connected to the hub of the needle. The tube is flexible and is pressurized so as to be blocked when the winged needle is pricked into tissue, and is released when hemodialysis or the like is carried out through the tube. The clamp of the present invention can pressurize the tube by the engagement of the engaging hooks provided on the upper member with the engaged portion provided on the lower member. The force of this engagement is bigger than the

force of repulsion of pressurized tube. On the other hand, the clamp of the present invention can release the tube from the pressurized condition by release of the engagement of the engaging hooks and engaged portion previously described. When the engaging hooks are not engaged with the engaged portion, the space between the engaging hooks and engaged portion is sufficiently large so as not to pressurize the tube and hemodialysis can be carried out through the tube.

The position of the Office regarding the second quoted recitation is that if the prior art structure is capable of performing the recited (intended) use, then it meets the claim. However, the safety clip of Chamuel is not capable of performing the mechanism of engagement performed by the clamp of the present invention as described above.

Chamuel states in Col. 3, lines 5-8, that a sliding surface 32 of a compression portion 30 (corresponding to the upper member of the present invention) exerts a force on needle 24 in a direction opposing the force exerted by the bottom 27 of guide means 28 (corresponding to the lower member). The needle is stiff and is not pressurized by that force. However, the force is large enough to fix the needle, and when the safety clip of Chamuel is installed on the needle, forces are directed in minimally two opposing

directions, at the same time, toward a common axis defined by the needle (described in Column 2 lines 28-53).

If the safety clip of Chamuel were to be used on a tube as in the present invention, the tube would be continuously pressurized by the force between the sliding surface and the guide means provided on the safety clip because the tube is flexible. Hemodialysis through the tube could not be carried out unless the safety clip was removed from the surface of the tube. On the other hand, if the force pressurizing the tube by the sliding surface and the guide means of the clip were modified to be small enough to carry out hemodialysis or the like through the tube, the tube cannot be pressurized and is not blocked when the winged needle is pricked into human tissue.

As explained above, the safety clip described in Chamuel is not capable of performing the intended use of the clamp of the present invention, and does not meet the claim. Therefore, the present invention having engagement hooks provided on an upper member and an engaged portion provided on a lower member as recited in claim 1 is structurally different from the clip of Chamuel and patentably distinguishes over the prior art.

Chamuel is also insufficient to support anticipation of new claim 3. Chamuel fails to disclose notches or holes provided on

the member opposite the "engaging hooks" 28' for engaging the engaging hooks. Moreover, such modification would be improper because it would destroy the invention on which Chamuel is based. The invention of Chamuel is a safety clip having a structure which avoids the need for engagement of the "hooks" of Chamuel with an engaged portion for the clip to engage a needle.

Removal of the rejection set forth in the Action and a notice of allowability are in order and are respectfully solicited.

The foregoing is believed to be a complete and proper response to the Office Action dated February 19, 2004, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

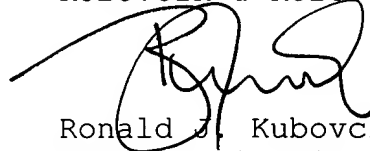
PATENT APPLN. NO. 09/870,583
RESPONSE UNDER 37 C.F.R. §1.111

**PATENT
NON-FINAL**

In the event any additional fees are required, please also
charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK



Ronald J. Kubovcik
Reg. No. 25,401

Atty. Case No. NPR-073
The Farragut Building
Suite 710
900 17th Street, N.W.
Washington, D.C. 20006
Tel: (202) 887-9023
Fax: (202) 887-9093
RJK/cfm